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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/547,997

09/12/2005

Patrick Alexandre

125042

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08/10/2007

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EXAMINER

MACNEILL, ELIZABETH

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

08/10/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/547,997

Applicant(s)

ALEXANDRE ET AL.

Examiner

Elizabeth R. MacNeill

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 7/27/07.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Objections***

1. Claim 1 is objected to because of the following informalities: lack of antecedent basis for "the inner wall" in the last paragraph of the claim. Appropriate correction is required. Additionally, based on the specification, the "inner wall" should be identified as the "transverse wall" (40) as shown in the Figs 6-7.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Rutkowski (US 3,308,818).

Rutkowski teaches a needleless injector with a body (10) forming a circuit consisting of an initiation device (30), a pyrotechnic gas generator (22a), a reservoir (16), and a combustion chamber (space proximal of the membrane), the combustion chamber divided into two subvolumes (Fig 3), the second volume is the empty space distal of the charge 22a, and an expanding membrane (14). See Fig 1a and 3.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lell (US 7,160,265, also published as WO 01/97880) in view of Schwebel et al (US 3,802,430).

Lell teaches a needleless injector with a body (3) forming a circuit consisting of an initiation device (31), a pyrotechnic gas generator (19), a reservoir (5), and a combustion chamber (13), the combustion chamber divided into two subvolumes (Fig 5) divided by a wall with an aperture (69). See Figs 1 and 5.

Lell does not teach an expanding membrane, but instead teaching a sealed plunger (9). Schwebel teaches a pyrotechnic needleless injector with a furled membrane (42). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the membrane of Schwebel with the injector of Lell, as it would produce the predictable product of a combustion chamber sealed from the reservoir.

As to claims 3-6, Lell discloses burstable membrane 67 dividing a subvolume of the combustion chamber. The second subvolume is the space within the annular opening 69. As to claim 7, see cartridge 7 of Lell.

6. Claims 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lell and Schwebel as applied to claims 1-7 and 9 above, in further view of Bellhouse et al (US 6,328,714)

Lell and Schwebel do not disclose an L-shaped duct.

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Bellhouse teaches a needleless injector with a detonator (32, acting on 44), a wall (Fig 3) with an aperture offset from the longitudinal axis of the chamber, and a rupture disc (at 38) forming an L-shaped duct.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the L-shaped duct of Bellhouse with the injector of Lell and Schwebel, as it would produce the predictable product of a replaceable combustion chamber sealed from the reservoir.

### ***Response to Arguments***

7. Applicant's arguments with respect to claims 1-10 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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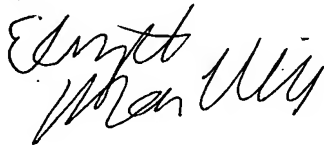
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM



KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

